To: Kingshuk Das[kdas@theranos.com]; Hui Wang[hwang@theranos.com]; Suraj Saksena[ssaksena@theranos.com]
Cc: Sunny Balwani[sbalwani@theranos.com]
From: Donald Tschirhart
Sent: Wed 3/30/2016 9:49:24 PM
Importance: Normal
Subject: Quality Committee Agenda Items from the inspection
Received: Wed 3/30/2016 9:49:24 PM
CMS Quality Items.docx

Quality Committee Agenda Items from the CMS Inspection

1) Evaluation of Proficiency Testing (PT)
2) Use of the PT corrective action form, CL FRM 00006-F1/F2
3) PT corrective action follow up: ALP, Blood Cell ID and Troponin
4) Handling of ungraded PT
5) Alternative Assessment Procedures (AAP) for PT evaluation.
6) Tracking of mislabeled specimens
7) Review of specimens referred to Reference Laboratories (RL)
8) TPS 3.5 shutdown
9) Signature of Laboratory Director(LD) on procedures prior to use
10) Monitoring of clinical lab freezer and refrigerator temps
11) Follow up on freezer temperature deficiencies.
12) Monitoring that other freezers and refrigerators are not used for the clinical lab.
13) Monitoring that package inserts are routinely reviewed for changes.
14) Monitoring test verification procedures, not performed by the manufacturer.
15) Criteria for test verification does not contain CV < 1.5 (manufacturer CV)
16) Monitoring assays for plasma testing were verified for plasma testing.
17) Documenting studies for reportable range were adequately performed.
18) Documenting where medical decision point replace reportable range.
19) Establishing and monitoring critical values.
20) Documentation of routine calibration verification and linearity studies.
21) Verification of licensing and monitoring of job descriptions for compatibility.
22) Documentation of training and competency
23) Monitoring that no patient results are reported without valid Quality Control (QC)
24) Monitoring use of the 10x rule
25) Monitoring of QC failures
26) Monitoring that parallel testing occurs when lots of QC material are changed.
27) Follow up Cellavison QC failure
28) Follow up CT/NG testing QC failure
29) Follow up bacterial media QC failure, document lot # used in patient testing.
30) Follow up HCG QC failure
31) Follow up LH QC failure
32) Follow up CEA QC failure
33) Monitor correct calculation of INR
34) Monitor comparisons of different methods or instruments performing the same test.
35) Monitor intra-observer variations in performing manual differentials.